

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,882	07/25/2003	Jong-Gu Park	57354-11USA	3831

7590 02/17/2006
JHK Law
P.O. Box 1078
La Canada, CA 91012-1078

EXAMINER

MARTINELL, JAMES

ART UNIT PAPER NUMBER

1634

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/627,882	Applicant(s) PARK ET AL.	
	Examiner James Martinell	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/19/04</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1634

Claims 19 and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 14, 2005.

Applicant's election with traverse of the requirement for restriction in the reply filed on December 14, 2005 is acknowledged. The traversal is on the ground(s) that the two Groups are related as product and process of use. This is not found persuasive because it is not clear that the unrelated and distinct genes mentioned in claims 19 and 20 are necessarily connected to any of the nucleic acid constructs or methods mentioned in the claims of Group I (*i.e.*, claims 1-18).

The requirement is still deemed proper and is therefore made FINAL.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague, indefinite, and incomplete.

- (a) The recitation of "distinct LC-sense molecules" (claims 1, 5, 8, and 13) is vague and indefinite because the instant application does not distinguish distinct molecules from indistinct molecules. In addition, the full term should be substituted for the abbreviation "LC".
- (b) The recitation of "LC-sense molecules" (claims 1 and 5) is vague and indefinite. The full term should be substituted for the abbreviation "LC".

Art Unit: 1634

- (c) The recitation of "LC-sense molecule" (claims 2 and 4) is vague, indefinite, and incomplete. The term is incomplete because there is no antecedent basis for it. In addition, the full term should be substituted for the abbreviation "LC".
- (d) The recitation of "LC-sense molecule" (claims 11 and 16) is vague and indefinite. The full term should be substituted for the abbreviation "LC".
- (e) The recitation of "said vector" (claims 3, 6, and 7) is incomplete because there is no antecedent basis for the phrase.
- (f) The recitation of "stably associated" (claim 8) is vague and indefinite because the instant application does not define the term.
- (g) The recitation of "different label" (claim 16) is vague, indefinite, and incomplete because the claim does not make it clear from what the label differs.
- (h) The recitation of "the LC-sense molecule in the array" (claim 16) is incomplete because there is no antecedent basis for the phrase.
- (i) The recitation of "such as" (claim 18) is vague and indefinite because it is not clear what the term is intended to mean or embrace as limitations.

Claims 6 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are not enabled because the instant application has not established whether each of the biological materials mentioned in the claims is permanently available to the public. Applicants' attention is directed to MPEP 2401-2411.05 and 37 CFR §§ 1.801-1.809.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant application

Art Unit: 1634

does not provide an adequate written description of the nucleic acid constructs mentioned in the claims. In *Vas-Cath v Mahurkar*, 19 USPQ2d 1111 (Fed. Cir. 1991) the court stated, "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (emphasis in the original) (*Vas-Cath* at page 1117). The instant application does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now claimed" (*Vas-Cath* at page 1116). In *Fiers v. Sugano*, 25 USPQ2d 1601 (Fed. Cir. 1993), the court also held that, "An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference a potential method for isolating it; what is required is a description of the DNA itself" (*Fiers v. Sugano*, page 1606). This view was reiterated in *Fiddes v. Baird*, USPQ2d 1481 (BPAI 1993) at page 1483, "If a conception of a DNA requires a specific definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity. . . . one cannot describe what one has not conceived." The court amplified this notion with respect to inventions claiming genetic material in *Regents of the University of California v. Eli Lilly*, 43 USPQ2d 1398 (Fed. Cir. 1997), stating at page 1406,

"In claims to genetic material, however, a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. . . . Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material."

Thus, since the instant application does not provide a description of the structure of the nucleic acid constructs mentioned in the claims, the application fails to meet the requirements of 35 U.S.C. § 112, first paragraph.

Art Unit: 1634

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, and 4 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Swaroop et al (Nucleic Acids Res. 19 (8), 1954 (1991)). Swaroop et al teaches the construction of single stranded cDNA libraries and the generation of single stranded circular DNA from the cDNA library (*e.g.*, see page 1954, column 1, lines 9-11 of the text and the Figure). Thus, the nucleic acid constructs of swaroop et al are embraced by the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719.

The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745.

OFFICIAL FAX NUMBER


The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Any Official Communication to the USPTO should be faxed to this number.

Art Unit: 1634

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


James Martinell, Ph.D.
Primary Examiner
Art Unit 1634

2/14/06